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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SEHARASEYON, JEGATHEESAN	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,732	EATON ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6,11-14 and 16-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6,11-14 and 16-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/20/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/20/2005 has been entered. An action on the RCE follows.

2. Claims 1-3, 7-10 and 15 are cancelled. Claims 4, 5, 6, 14, 16, 17 and 19 have been amended. Claims 21-31 have been added. Therefore, claims are 4-6, 11-14 and 16-31 are pending.

3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

4. The Office acknowledges the submission of the IDS dated 7/20/2005.

Priority

5. Based on the differential mRNA expression in the normal and tumor tissues disclosed in the PCT/US00/23328 filed August 24, 2000, Applicants are entitled to the priority date of August 24, 2000 for nucleic acids only based on the enabling disclosure.

35 U.S.C. § 101 Lack of Utility, withdrawn

6. Claims 4-7, 11-14 and 16-20 are rejected under 35 U.S.C. 101, as lacking utility, withdrawn. Specifically, Applicants assertion that the differentially expressed message can be used as a diagnostic tool for stomach, lung, kidney and melanoma tumors is found to be persuasive.

35 U.S.C. § 112, first paragraph, Enablement withdrawn

7. The rejection of claims 4-7, 11-14 and 16-20 under 35 U.S.C. § 112, first paragraph, for lacking support for either a specific and substantial asserted utility or a well established utility is withdrawn for reasons indicated above in paragraph 6.

35 USC § 112, first paragraph – Enablement, maintained

8. The rejection of claims 4, 5, 6, 14 and 21-27 under 35 U.S.C. 112, first paragraph, because the specification does not enable one of skilled in the art to which it pertains, or with which it is most closely connected, to make and/or use the invention commensurate in scope with these claims. The reasons for this rejection under 35 U.S.C. § 112, first paragraph, are set forth in the previous Office Actions (21 September 2004 and 20 April 2005). Specifically, SEQ ID NO: 119 fragments, polynucleotides that are 95 or 99% identical to such or to the full-length cDNA deposited as ATCC 203356, nor polynucleotides which hybridize to any of the above or complement thereof because there is no structural or functional information provided in the specification. In addition, the lack of direction/guidance presented in the specification regarding which variants of polynucleotides of SEQ ID NO: 119 encoded proteins would retain the desired activity, the complex nature of the invention, the state of the prior art establishing that biological activity cannot be predicted based on structural similarity, the absence of working examples directed to variants and the breath of claims, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Although, Applicants have amended the claims to assert that the nucleic acid is more highly expressed in normal esophageal or normal skin compared to esophageal tumor, lung tumor, normal kidney or normal skin compared to normal esophageal tissue, normal lung tissue, kidney tumor tissue or melanoma tissue, there is no way of knowing which, if any variants would have the same property of higher expression in the specific tissue. There is no nexus between the degree of homology and regulation of gene expression. Until one identifies a particular variant that demonstrates a higher expression or not, one of skilled in the art would not know the expression profile of the variant. Modifications to polynucleotides encoding the protein, e.g., by substitutions or deletions, would often result in deleterious effects to overall activity and effectiveness of the protein. Furthermore, it is also well known in the art that hybridization under moderately stringent conditions would yield nucleic acid molecules that are structurally unrelated.

Accordingly, the disclosure fails to enable such a myriad of the claimed nucleic acid molecules that not only vary substantially in length but also in nucleic acid composition and to provide any guidance to one skilled in the art on how to make and use the claimed genus of nucleic acid molecule. Thus, it would require undue experimentation for one skilled in the art to make and use the claimed genus of the molecules embraced by the instant claims. Therefore, the rejections of record are maintained.

35 USC § 112, first paragraph – Written Description, maintained

9. Claims 4, 5, 6 14 and 21-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention is maintained. The reasons for this rejection under 35 U.S.C. § 112, first paragraph, are set forth in the previous Office Action (21 September 2004 and 20 April 2005). Briefly, the Applicants were not in possession of all or a significant number of polynucleotides that have 95-99% homology to SEQ ID NO: 119 or the full-length cDNA deposited as ATCC 203356 or fragments of SEQ ID NO: 119 or those polynucleotide which hybridize SEQ ID NO: 33 or to the full length cDNA or deposited as ATCC 203356 or complements thereof and still retain the function of SEQ ID NO: 119.

Applicants discuss the legal standards applied when evaluating Written Description, including the requirement that written description depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure (pages 32, 20 July 2005). The examiner takes no issue with the discussion of general requirements for evaluating Written Description in this case. However, Applicants have not described or shown possession of all polynucleotides 95-99% homologous to SEQ ID NO: 119 or the full-length cDNA or fragments of SEQ ID NO: 119 or those polynucleotide which hybridize SEQ ID NO: 119 or to the full length cDNA deposited as ATCC 203356 and still retain the function of SEQ ID NO: 119. Nor have Applicants described a representative number of species that have 95-99% homology to

SEQ ID NO: 119 or those capable of hybridizing to SEQ ID NO: 119 or to the full length cDNA deposited as ATCC 203356 or complements thereof, such that it is clear that they were in possession of a genus of polynucleotides functionally similar to SEQ ID NO: 119.

As discussed in the previous Office Action (20 April 2005) even a very skilled artisan could not envision the detailed chemical structure of all or a significant number of encompassed polynucleotides, and therefore, would not know how to make or use them. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. The claimed product itself is required. Recitation of the phrase "wherein the isolated nucleic acid is more highly expressed in esophageal tumor tissue, lung tumor tissue or normal skin tissue compared to normal esophageal tissue, normal lung tissue, kidney tumor tissue or melanoma tumor tissue," (amended claims, 20 July 2005), is not adequate to describe polynucleotides of the instant invention that have 95-99% homology to the SEQ ID NO: 119 or the full-length cDNA or fragments of SEQ ID NO: 119 or those capable of hybridizing to SEQ ID NO: 119 or to the full length cDNA deposited as ATCC 203363 or complements thereof, since there was no reduction to practice to support the amended claims. Specifically, there is no way of knowing which, if any variants would have the same property of higher expression in the specific tissues. There is no nexus between the degree of homology and regulation of gene expression. Until one identifies a particular variant that is highly expressed or not, one of skilled in the art would not know the expression profile of the variant. The mere sequence alone will not allow one of

skilled in the art to predict expression. Applicants made no variant polypeptides, and as recited in the current Written Description Guidelines, Applicants must have invented the subject matter that is claimed and must be in "possession" of the claimed genus (Federal Register, 2001, Vol. 66, No. 4, pages 1099-1111, esp. page 1104, 3rd column).

Claim Rejections - 35 USC § 102 (new)

(f) he did not himself invent the subject matter sought to be patented.

10. Claims 4-6, 11-14, 16 and 21-27 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Based on Applicants provisional application (60/105002) disclosure, it appears that the instant cDNA is derived from the Incyte EST clone No. 3752657 (Appendix A, enclosed). Applicant states that "based on the DNA69561 consensus sequence and other information provided herein, a clone including another EST (Incyte DNA3752657) from the assembly was purchased and sequenced." Therefore, claims 4-6, 11-14, 16 and 21-27 rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Claim Rejections - 35 USC § 103, new

11. Claims 17-20 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Incyte DNA3752657 in view of in view of Jacobs et al. (U.S. Patent No: 5 965 397).

The teachings of Incyte DNA3752657 have been described above in paragraph 18. However, this Incyte DNA3752657 does not teach vector and host cells.

Jacobs et al. teaches a vector comprising the cDNA, a host cell thereof (claims 1-4 and columns 19, 20, 24, lines: 31-65). Therefore, it would have been *prima facie*

obvious to the person of ordinary skill in the art at the time the invention was made to obtain vectors (with control sequences) containing DNA sequences and transfecting them into host cells as taught by Jacobs et al. by cloning the cDNA that generates a polypeptide, that is at least 99% identical to SEQ ID NO: 119 of the instant invention from DNA described by Incyte DNA3752657. Further, Jacobs et al. have described the expression of nucleotides containing vectors with promoter sequences in bacterial hosts (columns 23-25).

The person of ordinary skill in the art would have been motivated to clone the nucleotide sequences described by Hillier et al. because it would allow for the expression of the polynucleotide and the subsequent characterization of the polypeptide. There is a reasonable expectation of success because transfecting the expression vector into host cell for the expression is routine in the art for expression studies and screen for new polypeptide. Therefore, the claims 16-20 and 28-31 are rejected as obvious over Incyte DNA3752657 in view of in view of Jacobs et al. (U.S. Patent No: 5 965 397).

12. No claims are allowed.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 9/05

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER

Appendix A Applicant's copy

The following examples are offered for illustrative purposes only, and are not intended to limit the scope of the present invention in any way.

EXAMPLES

Commercially available reagents referred to in the examples were used according to manufacturer's instructions unless otherwise indicated. The source of those cells identified in the following examples, and throughout the specification, by ATCC accession numbers is the American Type Culture Collection, Manassas, VA.

EXAMPLE 1

Isolation of cDNA clones Encoding Human PRO1573

EST 3628990 was identified in an Incyte Database, (LIFESEQ®, Incyte Pharmaceuticals, Palo Alto, CA) and extended in a comparison to other sequences in databases to form an assembly. The alignment search was performed using the computer program BLAST or BLAST2 [Altschul et al., Methods in Enzymology, 266:460-480 (1996)] as a comparison of the ECD protein sequences to a 6 frame translation of the EST sequences. Those comparisons resulting in a BLAST score of 70 (or in some cases, 90) or greater that did not encode known proteins were clustered and assembled into consensus DNA sequences with the program "phrap" (Phil Green, University of Washington, Seattle, Washington).

The consensus sequence is shown in Figure 3 (SEQ ID NO:3), and is designated herein "DNA69561".

Based on the DNA69561 consensus sequence and other information provided herein, a clone including another EST (Incyte DNA3752657) from the assembly was purchased and sequenced. This clone came from a breast tumor tissue library.

The entire coding sequence of PRO1573 is included in Figure 2 (SEQ ID NO:2). Clone DNA73735-1681 contains a single open reading frame with an apparent translational initiation site at nucleotide positions 97-99, and an apparent stop codon at nucleotide positions 772-774. The predicted polypeptide precursor is 225 amino acids long. The signal peptide is at about amino acids 1-17 and the transmembrane domains are at about amino acids 82-101, 118-145, and 164-188 of